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SUBJECT: POLAND: Embassy Warsaw Special 301 Input

Slow Progress, New Government

11. (SBU) Despite lingering problems in enforcement and, particularly, in judicial adjudication of optical disc (OD) piracy cases, there has been slow, but nonetheless steady, progress in Poland's handling of IPR violations, warranting maintenance of Poland's position on the Watch List. And while problems related to market access for pharmaceutical firms continue unabated, at this time we have no new evidence of specific IPR violations related to data exclusivity. That said, the legacy of problems dating back to poorly-enforced data exclusivity regulations continues to pinch the revenues of innovative firms, especially when combined with non-IPR related problems such as lack of access to the public health system drug reimbursement list. U.S. firms also point out post-accession additions to the so-called "ghost list" of market approved drugs, though not actually available, as they can be used to establish reimbursement prices well below that of the existing innovative drug.

Optical Disc Progress

12. (SBU) Secretary Gutierrez praised Poland's anti-piracy efforts and progress despite lingering problems in some areas (Ref K). Persistent efforts to encourage Poland's law enforcement to be more active, particularly at bazaars along the German border (Refs D, G, I) paid off last year not only with an increase in raids on pirates. Significantly, these efforts also provided the foundation for an industry initiative that brought legal experts from other EU countries to Poland, sensitizing the judiciary in south western Poland to the criminal nature of OD piracy.

13. (SBU) The December conference in Wroclaw, coordinated by the local Polish affiliate of the International Federation of the Phonographic Industry (IFPI) was noteworthy for several reasons, but mostly because it was a shining example of industry-government cooperation. It was this type of cooperative effort that the Polish government highlighted in its anti-piracy strategy (Ref D) released last spring. The increase in cooperation is evident from statistics of seizures of pirated goods.

Statistics

14. (U) Poland has made great strides in optical disk seizures over the past year starting in calendar year 2005. Compared to the previous year, the number of total cases increased from 1208 to 1221. Regions showing significant improvement indicated by an increase in the number of cases from 2004 to 2005 include: Lubuskie, Malopolskie, Swietokrzyskie, Zachodniopomorskie and Warszawa. The most impressive growth took place in the Warszawa and Malopolskie regions with an increase of 84 and 43 cases respectively when compared to 2004 data. In descending order, Polish authorities seized the largest number of foreign CDs, totaling 233,873 followed by CDR (95,853), MP3 (76,803), CD polish (60,179), DVDs (22,036), foreign cassettes (2,453), Polish cassettes (832) and CDRW (766).

15. (U) When analyzing the data, general trends emerge. For example, more CDs than cassettes were seized and more optical disks with foreign materials were seized when compared to purely Polish material. With regard to specific regions, Warszawa seized the largest number of foreign CDs (68,725) and Polish CDs (20,098) with the Malopolskie region coming in second with 17,411 Polish CD seizures. The most

pirated DVDs were found in the Malopolskie region (8433) with Warszawa coming in a distant second with 5550 DVDs seized in 2005. Seizures of cassettes are much lower than CDs, DVDs and MP3 materials due to improvements in technology. The largest number of seizures of Polish cassettes, foreign cassettes and MP3 pirated material took place in the Mazowieckie region: 215, 929, and 22,611 respectively. Lastly, the largest number of CDR seizures took place in the Zachodniopomorskie region with 23,332. Of note, aside from CDRW seizures in the Pomorskie and Dolnoslaskie region with 753 and 13 respectively, no other region seized any pirated CDRW materials. In discussions last year with Wroclaw police officials, they noted that college students burning CDRWs for profit is a particular problem in their area. The CDRW seizures in Dolnoslaskie appear to support their claims.

But Not All Is Rosy . . .

16. (SBU) Despite the evident progress, there are still several reasons why Poland should be maintained on the Watch List.

- Since the departure from the Ministry of Culture of a key contact active in anti-piracy efforts, and the relatively quick dismissal of his successor, it has been increasingly difficult to find someone who will take "ownership" of the piracy issue in this key government office.

- Related to this point, key elements pertaining to awarding damages of the EU Enforcement Directive are apparently being weakened in legislation currently under consideration.

- Although retail sales in the Warsaw Stadium have decreased, evidence indicates that the Stadium continues to serve as a "wholesale" distribution site.

- The judicial process, already slow and cumbersome, is backlogged with cases, and there appears to be limited interest in addressing some of the more egregious causes of prosecutorial sloth (such as procedural issues related to expert testimony, see Ref I). It should be noted that Poland's judicial system is equally inefficient in dealing with non-IPR commercial disputes.

- IFPI notes that Poland's production capacity has grown to 775 million units. The Embassy has visited the largest producer of CDs and DVDs in Poland (the Thomson plant outside Warsaw, which produces - for export -- OD media almost exclusively for major western firms) and is less concerned, given the current lack of evidence, with gross production capacity figures. We believe the real concern is the "missing" production line from Wroclaw, which somehow vanished from police storage as reported last spring.

Next Steps for OD

17. (SBU) In discussions with visiting MPA representatives, we outlined what we believe to be the most efficacious course of action in dealing with outstanding piracy issues. A stronger focus on legislative fixes to evidentiary requirements, an emphasis on stronger criminal penalties, and a strengthening, rather than dilution, of legislation when implementing EU directives are the most salient points. Further cooperation with industry (see Ref D) and the judiciary will, we believe, support these efforts most effectively.

Pharmaceuticals

18. (SBU) More thorny are the issues facing the pharmaceutical industry. The Polish government has been less than aggressive in protecting intellectual property (read data exclusivity) in the past; however, now we are dealing with the legacy of the ghost of the data exclusivity past, with no strong evidence of new violations of TRIPs obligations being brought forth. It is understandable that the innovative drug industry is frustrated with its lack of market access, but we believe the best way to assist the industry is to focus on tangible issues we can attack now, rather than go through the repetitive and less effective process of reminding the Poles of their international obligations (Ref J).

19. (SBU) As Secretary Gutierrez noted in his discussions with both industry representatives and Health Minister Religa, the biggest obstacle for innovative firms is lack of access to the public health system drug reimbursement list. Attacking the Poles on older cases related to data exclusivity deficiencies will not address this problem.

The Issues

10. (SBU) As noted, the lack of access to the reimbursement list means that innovative drugs are paid for by the Polish health care consumer 100 percent out of pocket. Although, by our count, four new molecules were added to the reimbursement list last year, these were the first additions to the list in seven years. With the lack of innovation represented in the reimbursed Polish pharmaceutical market, it is at the same time astounding to realize that Poles pay more for prescription medicines than any other EU country.

11. (SBU) In addition, the still unresolved Customs and Margins case (see Refs A,L) creates tremendous uncertainty for innovative firms, most of which import their products. Additional troubling calls from the Health Ministry for cost of production data (a complete non-starter for most of innovative firms) raises the spectre of a new rash of problems with data exclusivity, given Poland's problematic track record of protecting data in the 1990s.

And Where We Go From Here . . .

12. (SBU) Nonetheless, these problems have less to do with strict IPR-related issues than they do with tremendous market access obstacles. As noted in Ref L, we believe the best way to address these issues is with increased dialogue with Ministry of Health officials, which now seems to be a real possibility.

13. (SBU) In discussions with Secretary Gutierrez, Minister Religa offered to have the Health Ministry engage in dialogue with the innovative drug industry. To that end, the Embassy is working with the Pharmaceutical Committee of the AmCham to invite Religa to the March 2-3 meeting in Warsaw of the chief executives of major innovative firms. The Ambassador is conveying directly the importance of the meeting to the Minister.

14. (SBU) In any event, we hope to establish an "institutionalized dialogue," perhaps on a monthly basis, between industry and the Ministry. The receptivity of the Minister to transparency and dialogue during the Gutierrez visit is something we believe should be pounced on. At the same time, we believe maintaining Poland on the Watch List will provide us with leverage, should problems related to cost of production data move forward. Keeping our powder dry and testing the Ministry's willingness to engage in fruitful discussions is, we believe, the proper course of action.